

Military Medical Research News

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Nurses use research, inquiry to improve patient care Science, evidence-based practice make ripples across hospital

by Paula Amann

Manuel “Manny” Santiago, a clinical nurse specialist with 32 years in military hospitals, is probing whether use of a peripheral intravenous bundle cuts complications. Navy Cmdr. William Danchanko, a veteran oncology nurse, is studying how shrapnel lodged in the human body impacts bone growth. Sarah Coughlin, a doctoral student in nursing practice, is testing a protocol that would help nurses ease symptoms sooner for emergency room patients with low risk but high pain.

If these three generations of nurses have a common bond, it’s their passion for improving the quality of patient care at Walter Reed National Military Medical Center.



Army Lt. Carolina Bardales, a registered nurse in the cardiology inpatient unit at Walter Reed Bethesda, readies final medications for Denise Toyer, before she goes home on Feb. 10 after a successful procedure. The yellow sash worn by Bardales signals “no interruption,” an innovation pioneered by nurses Manuel Santiago and Army Maj. Christina Moore that has helped cut medication errors at the hospital. (Photo by Paula Amann)

Nursing research is about creating new science. Evidence-based practice (EBP) and quality improvement (QI) is about translating new-found science to the bedside.

The number of nurses within the hospital testifies to the role they can, and do, play in its ongoing improvement. As of 2013, there were 535 military and civilian registered nurses at work, aided by 600 licensed professional nurses and other paraprofessionals, according to the Directorate of Nursing’s most recent figures. And that’s not counting contractor nurses, like Coughlin, who supplement this staff.

Nurses bring a unique outlook to medicine, believes Danchanko, chief of the Center for Nursing Science and Clinical Inquiry at the hospital. Among other roles, the nurse serves as a “gatekeeper” to services for the patient, from a doctor’s counsel to dietary advice, physical therapy and social work, he says.

“Nursing ends up being the cornerstone of care,” Danchanko said. “We’re the ones who spend the most time with the patient.”

As a result, nurses may look at quality improvement with a more “holistic” view than others in the health care system, Danchanko contends. For example, he notes, when providers reduce the length of patients’ hospital stays, they can drive down rates of infection and illness, as well as costs for all concerned.

“Nothing in a hospital happens in a silo,” Danchanko said. “If you can do one good thing, you’re going to end up having multiple effects on many different levels.”

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DEPARTMENT OF RESEARCH PROGRAMS



Army Col. Peter Weina, chief of Department of Research Programs (official photo)

The Department of Research Programs (DRP) at Walter Reed National Military Medical Center supports research activities in the National Capital Region (NCR) through regular news.

This monthly newsletter covers events, research and administrative policies and procedures, research studies and collaborations, department operations, workshops and other NCR initiatives.

MILITARY MEDICAL RESEARCH NEWS

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This newsletter appears monthly. We welcome your story ideas, comments, corrections and photographs (action shots are best). Please send any timely information by the 15th day of the prior month for the following month's issue. Send your ideas, pictures or infographics to paula.m.amann.ctr@mail.mil.

RESEARCH FIRST STEPS

Our protocol navigators are available to help you start the process and assist you with your submission. To make an appointment with a protocol navigator, please call the Department of Research Programs (DRP) office at 301-295-8239. DRP is located in Building 17B, on the third floor, to the left of the elevators.

RESEARCH ROUNDTABLE SCHEDULE

Walter Reed National Military Medical Center

America Building (Building 19), Second floor, Room 2301

- ◆ Tuesday, March 21, 1200-1300
- ◆ Tuesday, April 18, 1200-1300
- ◆ Tuesday, May 23, 1200-1300

Did you miss the last roundtable? Please see story and a preview of our next presentation on page 12.

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COMMAND CORNER

The Department of Research Programs has had quite a lot of disruption and turmoil over the last several months. Our people have survived multiple audits, recent changes in leadership and the continuing challenge of the electronic Institutional Review Board, or EIRB.

We are committed, though, to fostering excellence in research at the flagship of military medicine, while protecting those who are modern-day heroes by volunteering to participate in research here. As we approach our first anniversary with EIRB, I can say with confidence that we are making this a functional and useful system. We could only have done it with your help and dedication.

Meanwhile, it is with regret that I announce the move of Army Col. Ann Nayback-Beebe away from being my deputy and into a more active role in the Center for Nursing Science and Clinical Inquiry as senior nurse scientist and exempt determinations officer. We owe a tremendous debt to Nayback-Beebe for her selfless devotion to the department over these last few difficult months. I, for one, salute her exceptional service.

Thanks again for your patience during this past year's transition to EIRB. Meanwhile, our best wishes for a great month of research.

Army Col. Peter J. Weina



Advancing your research online

Quick tips for the Electronic Institutional Review Board

Update your email.

Principal investigators, you must update the primary email address in your User Profile for the Electronic Institutional Review Board, or EIRB, to either your “mail.mil” email or your best contact email address. Other research team members should do the same.

First, visit https://ssopt.csd.disa.mil/amserver/UI/Login?org=cac_pki&authlevel=3. Secondly, click on the “Update your Enterprise Profile” link on the bottom left. Log in with your common access card, or CAC. A new screen will appear with four blank boxes, where you can enter your primary and alternate email addresses. Finally, click the “Update E-mail” button to save your changes. Once this is done, please log into the EIRB system and update your profile with the correct information.

Track your training.

Please upload certificates for the CITI training for all investigators, research monitors and other research staff. For CITI, recall that the Office of the Under Secretary of Defense (Personnel and Readiness) [OUSD (P & R)] is the accepted affiliation. Meanwhile, your exact requirements for CITI training depend on your research role. If the training feature in EIRB is not yet functioning, you may upload your certificates with your CV.

Revise your resume.

Make sure your EIRB User Profile has a recent version of your signed and dated resume, curriculum vitae or biographical sketch. Please check that the version information you enter in EIRB matches what appears on any document you upload into the system.

Pinpoint your status.

In an EIRB Continuing Review submission, choose only one “study status.” In other words, your study is either open to accrual or closed to accrual. It cannot be both.

Name it right.

Our system has a Submission Component Naming convention for documents. Please note: The version information will automatically populate in the Submission Components area when you enter the document's version information in EIRB. Again, check that the version information you enter in EIRB matches what appears on any document you upload into the system.

Please use intuitive titles, labels and names for documents such as consent forms that you upload into EIRB. For instance, if you have more than one consent form, say so. You might label them like these examples: Consent Form Study Group or Consent Form Control Group; Consent Form with tracked changes or Consent Form clean, no tracking.

If you have more than one HIPAA authorization, your entry should reflect that. For instance, you might enter HIPAA Authorization Study Group or HIPAA Authorization Control Group.

For any Data Collection Form, insert the precise form title. Examples might include Demographic Form or ABC Collection Form. If your study has more than one questionnaire, make that clear. You might label one “Questionnaire_Sleep Habits” and another “Questionnaire_Demographic Information.”

Do you have multiple recruitment and study flyers? If there is more than one, say so, as in “Recruitment Flyer_DEERS Beneficiaries” and “Recruitment Flyer_non-DEERS Beneficiaries.”

Take care in labeling documents related to research team members. Here are some examples: CITI_PI LTC John Doe, CV_PI LTC John Doe, CITI_AI CPT Joe Doe, and CV_AI CPT Joe Doe.

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DEPARTMENT ANNOUNCEMENTS

Apply now for Aware for All, Spring Research Summit

The Department of Research Programs is hosting the 5th Annual Aware for All and Spring Research Summit at Walter Reed Bethesda in May 2017, as part of Research and Innovation Month. Find documents needed to apply for both at <http://www.wrnmmc.capmed.mil/ResearchEducation/ResearchPrograms/SitePages/ImportantDocs.aspx>

Aware for All will take place May 16, from 1100 to 1400 in the lobby of the America Building (Building 19). Groups will display their research to the public and offer participation opportunities to those interested. Spring Research Summit will take place in the Memorial Auditorium (Building 2) on 24 May, from about 0800 to 1300. Speakers will present on topics ranging from ongoing research to funding and opportunities for collaboration. Join us in May.

Researchers win major funding

The Business Cell helped Navy Capt. Robert Browning win the Clinical Research Intramural Initiative Program's Precision Medicine Award. This \$954,144 award from the Congressionally Directed Medical Research Programs will support the project, "Genomics of Early Lung Cancer Among Military Personnel," for which Browning is principal investigator.

To follow up on the three-year award, Walter Reed Bethesda is teaming up with the Uniformed Services University of the Health Sciences, which in turn will facilitate partnerships between the American Council of Radiology, Brown University and the Henry M. Jackson Foundation.

Another new grant of \$153,500 will go to Douglas Brungart, an audiologist at Walter Reed Bethesda, under the auspices of the DHP 6.7 award for Clinical and Rehabilitative Medicine. This will support Brungart's project to test the use of a commercial virtual reality system for rehabilitating wounded service members with multiple sensory injuries in mobile military treatment centers. Keep an eye out for other research funding opportunities. □

Interested in data analysis?

**Let the biostatistics team at the Department of Research Programs help.
With two weeks' notice, we can lecture on many topics for you and five or more people:**

- *Introduction to statistics (including types of variables, hypothesis testing)*
- *Sample size estimation*
- *Multiple comparisons between groups*
- *Confidence intervals*
- *Randomized clinical trials – the Consolidated Standards of Reporting Trials (CONSORT) checklist*
- *Clinical research design (including retrospective, prospective and case control)*
- *Diagnostic tests for sensitivity and specificity*
- *Estimating reliability between raters*
- *Odds ratios and relative risks*
- *Regression analysis*
- *Principal component analysis and factor analysis*
- *Introduction to Statistical Package for Social Sciences (SPSS)*
- *Analyzing with Excel (including pivot tables, row and column calculations, and graphing)*
- *New this year: Introduction to R (a statistical programming language)*

Got questions? Suggestions? Ready to schedule a class?

Contact Ms. Sorana Raiciulescu at sorana.raiciulescu.ctr@mail.mil



HOT TOPICS IN COMPLIANCE

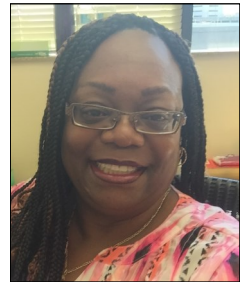
Is a Delegation Log Required?

by Diane Beaner, compliance officer

Answer: No, but it's really helpful.

Although federal regulations do not require a delegation log, good clinical practice suggests documentation when the principal investigator has delegated tasks to other members of the research team. Here are examples of these tasks:

- ◆ Screening of subjects
- ◆ Interpreting screening results
- ◆ Obtaining informed consent of subjects
- ◆ Receiving, handling or administering study agents
- ◆ Reporting (including safety reporting) and transcribing data
- ◆ Reviewing clinical results and other laboratory tasks
- ◆ Entering data
- ◆ Archiving study data



Diane Beaner, research compliance officer
(Photo by subject)

What is appropriate delegation of study-related tasks?

The principal investigator (PI), is ultimately responsible for the conduct of the study, but can delegate certain tasks to other members of the research team, such as associate investigators, research nurses, coordinators and lab personnel.

When delegating study tasks, the PI must choose the right team member:

- ◆ The person must be qualified by education, training and experience to perform the task.
- ◆ The person must have relevant medical training and, when appropriate, licensing or certification.
- ◆ The person has time to do the job.

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TIPS, from page 3

Parse your populations.

Please be mindful of any section instructions for a Template or Form, as the instructions can offer guidance on what information the reviewers are seeking. For example, the EIRB protocol application has separate sections for Target Population and Subject Population. Often, researchers enter the same information in both sections, losing the distinction between them. Similarly, section 14.5, Privacy for Subjects, differs from section 14.3, Confidentiality Protections.

Check your calendar.

Know the due dates for continuing review of your research protocols.

List your team members.

You can add and delete the Protocol Contacts (read-only access) and the Department Heads (read-only access) without an IRB submission by going to the Study Management tab and selecting Key Personnel. It will allow you to add users for these roles only.

On the other hand, to add new principal investigators, associate investigators and research support staff who have read-and-write access, you must submit a Modification Submission Form via EIRB for IRB review and approval. □

– Compiled from tips by Wendy Gilbert, IRB manager; Angela Drago, research support specialist – IRB; Vicki Miskovsky and Deborah Kessler, protocol analysts; and Robert Roogow, director of IRB operations



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For instance, if research by nurses could confirm the value of complementary medical treatments for pain, these alternatives could help cut the risk of opioid abuse and overdoses due to polypharmacy.

Lower back pain is among the most frequent reasons for medical visits, lost work time, and absence from garrison duty and combat, reported nurse scientist, Army Col. Ann Nayback-Beebe.

“Studying better ways to treat pain without the use of opioids was a key recommendation of the Army Surgeon General’s 2011 Pain Task Force Report,” added Nayback-Beebe, “and the main reason I chose to study pain and treatment outcomes.”

Given those outcomes, Nayback-Beebe, deputy chief of the Department of Research Programs and its chief of protocol development, is exploring the potential of pulsed



Army Col. Ann Nayback-Beebe, deputy chief of the Department of Research Programs (Photo by John Fadoju)

electromagnetic frequency (PEMF) therapy and other forms of electroanalgesia, like scrambler therapy, to treat chronic lower back pain.

Scrambler therapy is a pain management approach that delivers electrical impulses through the skin to block the transmission of pain signals by providing non-pain information to nerve fibers that are receiving pain messages.

Nayback-Beebe’s pilot study suggested that use of PEMF as an adjunct treatment made only small improvements in pain

symptoms and overall functioning but significantly boosted physical health-related quality of life among service members.

However, she also discovered significantly higher anxiety symptoms in service members treated with PEMF, which is previously unreported in the literature.

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► *Note: People who perform only standard-of-care procedures and are not part of the research team (e.g., electrocardiogram technician and hospital nursing staff) need not be listed on the Delegation of Authority log.*

When conducting an FDA-regulated research study, the PI will assume full responsibility for the clinical investigation, regardless of any tasks delegated to others.

- ◆ This is documented by the PI’s signature on the FDA Form 1572 for investigational drug research, or on the Investigator’s Agreement for research using an investigational device.
- ◆ The PI may select other investigators to assist with a study. These investigators may conduct procedures and activities required by the protocol under the supervision of the PI. Investigators must be listed on the FDA Form 1572 or Investigator’s Agreement, but are not required to sign the Form FDA 1572 or Investigator’s Agreement.

Examples of inappropriate delegation of PI responsibilities

- ◆ Over-delegating of work to nonphysicians (example a person with inadequate medical training conducting screening evaluations, obtaining medical histories and assessing inclusion criteria)
- ◆ Delegating a person who is already overloaded with tasks
- ◆ Assigning a person to assess a crisis when they are looking to the PI for leadership (e.g., assessment of adverse events, and knowledge of the investigational product)
- ◆ Delegating the task of obtaining informed consent to a person who lacks needed medical training, knowledge of the clinical protocol or familiarity with the investigational product ▣



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“The goal of the pilot study was to test the acceptability of the treatment, examine the effect of the intervention on multiple biopsychosocial variables, and obtain preliminary data to inform a larger study,” Nayback-Beebe said.

The next step: Nayback-Beebe has received funding for a larger randomized controlled sham study.

When asked “Why this treatment, why now?” Nayback-Beebe responded, “We need to put effective pain treatments in the hands of the service members so they can treat their pain symptoms when and where they occur, even down range.”

Managing acute pain symptoms early and aggressively is an important way to prevent service members from progressing to chronic pain states that can significantly degrade their physical, mental, and social health and well-being.

Nurses with doctoral training, like Nayback-Beebe and Danchanko, offer special strengths to medical research, said Navy Cmdr. Virginia Blackman, the former chief of the Center for Nursing Science and Clinical Inquiry.

“What nurses bring to research is Ph.D. training in the philosophy of science, training in multiple research methodologies and our holistic orientation as nurses,” said Blackman, who earned her own doctorate two years ago.

Blackman is an assistant professor in the doctoral program of the Daniel K. Inouye Graduate School of Nursing at the Uniformed Services University of Health Sciences. She pointed to the breadth of research projects launched by nurses, noting that it reflects the individual expertise of each scientist.

“We do research wherever our particular areas of expertise fit the needs of the military and our particular command,” Blackman said. Nurses at Walter Reed Bethesda, she noted, have probed such varied research problems as health policy, post-anesthesia delirium and children’s adjustment to their parents’ tours of duty.

Also illustrating the impact of nursing inquiry are evidence-based practice projects. One such effort seems to have helped cut medication errors at Walter

Reed Bethesda. Santiago and Army Maj. Christina Moore, both nurses, spearheaded the effort, dubbed the Must Eliminate Distraction Zone, or MED Zone.

Moore learned of medication errors in San Antonio, where she made the MED Zone project her master’s thesis at the University of the Incarnate Word.

A nursing colleague reported responding to a doctor’s abrupt summons while collecting medications for a patient, Moore recalled. When the interrupted nurse returned to her task, she entered the wrong patient room and dispensed the drugs prescribed for a different patient.

“Just hearing those stories made me realize how we’re so conditioned to interruptions as nurses, we think it’s the norm,” Moore said.

The research literature lends support to such anecdotes, Moore noted. A 2010 study by Patricia Trbovich et al. of nurses in the chemotherapy unit of a Toronto hospital showed interruptions were rampant.

In fact, nurses were interrupted during more than one-fifth – 22 percent – of their work time. What’s more, these interruptions often happened during “safety-critical” moments such as vital sign checks, drug verifications and intravenous push tasks (for giving medicine).

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Army Maj. Christina Moore, a clinical nurse specialist in the surgical units, discusses evidence-based practice with Manuel Santiago, who is also a clinical nurse specialist. Their joint efforts to cut medication errors helped Must Eliminate Distraction Zone, or MED Zone in units across Walter Reed Bethesda. The 10-point system, which includes a yellow sash, alerts staff, patients, and family members that a nurse is dispensing medication and cannot be disturbed. (Photo by Paula Amann)



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Even Walter Reed Bethesda was dealing with similar issues, it seemed.

“Our nurses were having three to four distractions per medication pass,” recalled Santiago of the baseline data he and Moore collected prior to their project.

To reduce such interruptions, the research duo devised a rich set of visual cues and action steps for nurses on medication duty. They don a yellow sash visible from all directions, avoid conversation (unless it concerns medicines), prioritize medication tasks and administer meds to only one patient at a time. And these are just four of 10 steps on the MED Zone checklist.

“When you see the obnoxious yellow belt, you know I’m doing an important job and don’t interrupt me,” Moore said.

She and Santiago started small at first, implementing MED Zone in three units of Walter Reed Bethesda.

“Those units had a 36 percent reduction in medication administration errors and a 60 percent reduction in distractions,” Santiago said.

Eventually, with the support of hospital leaders, the practice took hold across most inpatient units of the hospital. Today, these units sport burgundy mats with “MED Zone” in silver letters on the floor of the medication area.

“We have noticed a lot of decrease in medication errors,” said Army Lt. Col. Paul Ware, the service chief for inpatient cardiology at Walter Reed Bethesda, where Santiago works.

And now, to reduce infections, Santiago has a new evidence-based practice project to fine-tune use of intravenous bundles.

Across the hospital, in the emergency room, Coughlin is piloting a pain protocol for use by triage nurses in the emergency room, like herself. She aims her quality improvement and doctoral project at low-risk patients who suffer from painful sprains, strains and non-protruding fractures.

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Center supports nurses as they seek to study, strengthen medicine

Nestled on the fourth floor of building 17B, the Center for Nursing Science and Clinical Inquiry (CNSCI) supports efforts to boost clinical practice and research in all fields of nursing. This work, in turn, sets the scientific foundation for the care of service members and their families.

“Research is essentially changing the science behind the way we practice,” said Navy Cmdr. William Danchanko, the center’s chief.



Navy Cmdr. William Danchanko, chief of the Center for Nursing Science and Clinical Inquiry, on the terrace of Building 17B last spring (Photo by Paula Amann)

The center’s research portfolio and methods expertise span health and illness across inpatient and outpatient settings. The center also encompasses pre-deployment, deployment and post-deployment topics.

When nurses have an idea they wish to explore, the CNSCI can help. Nurse scientists can assist with developing study ideas, designing and implementing research studies, assisting with protocol and grant writing, and guiding preparation and submission of protocols to the Institutional Review Board.

Center staff can also help craft surveys, analyze and interpret data, and present data. Staff members have published extensively in peer-reviewed journals and presented work at international and national conferences. So, they are also available to aid in dissemination of research and project findings by coauthoring or editing manuscripts, abstracts, and podium or poster presentations.

While the center encourages research, quality improvement and evidence-based practice projects by nurses, Danchanko also sees his role as a “gatekeeper” for those planning these projects and an advocate for the patients who volunteer to take part in studies.

“There’s only so much burden we can put on research participants, from an ethical standpoint,” Danchanko said. “How many amputees have to fill out a questionnaire?”

The center saw changes after Walter Reed Army Medical Center and the National Naval Medical Center merged in 2010-2011. Once home to five staff members, it now has one full-time and one half-time staff, Danchanko noted.

“With a shortage of nurse scientists in the Army, the Army Nurse Corps has begun moving their complement of nurse scientists into centers at the major Army military treatment facilities,” added Army Col. Michael Schlicher, consultant to the Army Surgeon General for Nursing Research.

As a part of the recently created Defense Health Agency, the center no longer strictly fits the model for either Army or naval institutions, observed Navy Cmdr. Virginia Blackman, the center’s past chief. She is now an assistant professor in the doctoral program of the Daniel K. Inouye Graduate School of Nursing, at the Uniformed Services University of Health Sciences.

“Finding the right way for this organization, the DHA way – not an Army way or a Navy way – would maximize the value of nurse scientists to the organization,” said Blackman. □



From NURSES, page 8

“It’ll help the whole ER by decreasing the length of stay,” Coughlin said, noting that a similar study showed a surge in patient satisfaction.

“The whole ER system is based on priority,” said Coughlin, who is a nurse practitioner. “If you’re a lower acuity patient, say a 4 or 5, you’re going to have a longer wait to see a provider.”

Generally, she notes, patients will see a triage nurse within 15 minutes of arriving in the emergency room. And what better staff member, she thought, to offer them some early pain relief, through an ice pack, sling, ibuprofen or acetaminophen — depending on the level of reported pain.

Getting analgesia to patients sooner, suggests Coughlin, could reduce the time they have to spend in the emergency room and boost the way patients score their care.

“It’ll help the whole ER by decreasing the length of stay,” Coughlin said, noting that a similar study showed a surge in patient satisfaction.

To gauge the success of her quality improvement project, Coughlin developed a set of forms, including an intake sheet for each patient, a nurse evaluation of the protocol and a brief patient satisfaction survey.



In the Emergency Room, registered nurse, Thea Moss, reaches for an ice pack, one of several tools for pain relief urged for use by triage nurses with low-acuity patients in Sarah Coughlin’s quality improvement project. (Photo by Paula Amann)



Sarah Coughlin, a nurse practitioner in the Emergency Room at Walter Reed Bethesda, checks pain medications. As part of her doctoral program, Coughlin is piloting a protocol for triage nurses like her. The project’s goal is quality improvement by getting quicker pain relief to low-acuity patients. (Photo by Paula Amann)

Although Coughlin chose to adapt her project to her unit at Walter Reed Bethesda, she stresses that other nurses can launch similar ones in other corners of the hospital.

“You can do QI [quality improvement] wherever you’re working,” Coughlin said, noting that the key to project design is simple: “How can we improve the care for our patients?”

Even informally, nurses at Walter Reed Bethesda are bringing that question to other departments. Ware, the cardiology service chief, noted a spike in patient falls around New Year’s Day, 2015. He responded by moving high-risk patients near the nurses’ station and making it a staff priority.

“Nobody in my career talked about falls at the huddle,” said Ware, referring to the daily meetings between departing and arriving shifts of health care providers.

Over the past year, he has addressed the oversight. With a new focus on prevention at the huddle and across the unit, the number of falls in the cardiology unit decreased by 54 percent, he reported.

What’s the next frontier in nursing research and inquiry? Danchanko sees that horizon in palliative care, which offers patients with serious illnesses relief from pain, symptoms and stress.

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DARNALL MEDICAL LIBRARY

Research and Scholarly Communication Support

Lyubov Tmanova, DVM, MLIS, MS, informationist/biomedical research librarian, offers research support to Walter Reed Bethesda's biomedical community and helps integrate biomedical information into medicine to advance research and scholarly communication. She offers research-oriented classes on a quarterly basis. Individual and group consultations are available upon request.

Research and Scholarly Communication Classes ■ Building 5, Room 4011

MARCH

Preparing Your Manuscript for Publication

Tuesday, March 14, 12-1 p.m.

This workshop is focused on planning, writing, and submitting manuscripts for publication in biomedical journals. Students will be guided through the publication process, journal selection, and authorship guidelines and standards. The workshop also covers steps and tips for writing a compelling manuscript (title, abstract, introduction, methods, materials, results, and discussion). The manuscript submission and review, copyright, research integrity, and public access policy compliance will also be discussed.

Writing Systematic Reviews

Thursday, March 16, 12-1 p.m.

This workshop provides an overview of the purpose, structure, components, and writing process of systematic reviews. Attendees will learn systematic reviews standards and guidelines, and explore working with librarians (details on Systematic Review Service page).

Preparing Your Manuscript for Publication

Tuesday, March 21, 12-1 p.m.

This workshop focuses on planning, writing, and submitting manuscripts for publication in biomedical journals. We take authorship guidelines and standards. The workshop's writing section is centered on steps and tips for writing a compelling manuscript.

Designing a Compelling Scientific Presentation

Tuesday, March 28, 12-1 p.m.

This workshop will help you to structure and design your research presentation using the key elements of scientific presentation to communicate your research findings to your audience.

Contact: Lyubov Tmanova, DVM, MLIS, MS

Informationist / Biomedical Research Librarian

Darnall Medical Library, Building 1, Room 3458

Phone: 301-319-2475 ■ Email: lyubov.tmanova.civ@mail.mil

Website: www.wrnmmlc.libguides.com/home/researchsupport

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"I can treat someone's cancer with chemotherapy, while managing their spiritual care and their shortness of breath," Danchanko said, illustrating how a palliative approach might work in real life.

At Walter Reed Bethesda, the range of palliative care ranges from the uplift of art and music to the comfort of chaplains and service dogs.

"All of these things can improve the quality of life," Danchanko said. "At the end of the day, palliative care strives for that."

Looking ahead, Danchanko said he would like to see his field better gauge the impact of this palette of services on patients and their families.

The chief of the Center for Nursing Science and Clinical Inquiry flagged as worth exploring the perceptions and use of palliative care among service members, as compared with civilians.

In addition, he would welcome research on how to boost access to this form of care for relatives of service members, too. □



Palliative care at Walter Reed Bethesda includes service dogs like Archie, seen at his retirement March 8. Behind him, from left, are Army Sgt. Alisha Kohler, an unidentified man and Amy O'Connor, a volunteer coordinator for service dogs (Photo by Spc. Dakota Holtman)



DEPARTMENT DOWNLOAD

NEWS FROM THE DEPARTMENT OF RESEARCH PROGRAMS

At the Feb. 2 meeting of the Department of Research Programs, or DRP, Deputy Chief Army Col. Ann Nayback-Beebe addressed a few topics of interest to the broader research community.

First, a recent audit of the DRP and some key clients underscored the need for principal investigators, or PIs, to understand and meet their responsibilities. The PI guide available on the department's intranet site under DRP Policies and Procedures outlines these responsibilities in detail.

In addition, the department leaders urge researchers to submit their continuing reviews on time. When studies expire, this can inadvertently signal to the Institutional Review Board that PIs are not handling their responsibilities as required. Timely submission, on the other hand, builds confidence in a research project and its leadership team.

Amid the ongoing challenges of the electronic Institutional Review Board, or EIRB, the DRP nominated Erica Reid, a research protocol specialist, as civilian of the quarter. In comments on the nomination form, the nominating committee cited Reid's "high productivity and detail-oriented research reviews" as crucial factors. Beyond these strengths, the committee heralded her role as a "positive and proactive force in implementing the new EIRB system."

Leaders as diverse as Dr. Paul Pasquina, chief of the Department of Rehabilitation, and Army Lt. Col. Brandi Ritter, branch chief of the Research Regulatory Oversight Office for the Defense Health Agency, lauded Reid for her patient support to research teams on the new system. A final winner for the honor will likely emerge in the coming days.

In other staff news, Robin Howard, the supervisory statistician with DRP, became deputy chief of the department as of March 1. Also this month,

Col. Ann Nayback-Beebe stepped down from her role as deputy chief, while assuming duties as determinations officer, publications clearance reviewer and senior scientist with the Center for Nursing Science and Clinical Inquiry

In a move designed to strengthen continuity, Robin Howard, a biostatistician, took the helm as the new deputy chief of the Department of Research Programs.

(see story about the center on page 8). She will help coordinate this year's Research and Innovation Month, which kicks off on May 1.

The goal of the deputy chief leadership change from a military service member to a civilian supervisor is to provide greater continuity and stability within the department, Nayback-Beebe said. As part of DRP's restructuring,

veteran protocol analyst, Verna Parchment, was also named as chief of the Protocol Development Section.

While Army Col. Michael Schlicher remains on staff with the Center for Nursing Science and Clinical Inquiry and works with the Army Surgeon General, he is serving as acting chief of the Biomedical Research Laboratory while

its chief, Army Capt. Franz Frye, is doing leadership training.

Meanwhile, Army Col. Peter Weina, the department's chief, is filling in for Martin Hindel, the acting chief of the Business Cell and its research attorney, while Hindel fulfills his Air Force reserve duty. In the meantime, Jelena Gvozdenovic-Jeremic will field any questions about

technology transfer and partnership agreements. Lisa Potts will handle questions about grants. ▣



Erica Reid, a research protocol specialist, was nominated as employee of the quarter for Walter Reed Bethesda (Archival photo by Paula Amann)

– Paula Amann



RESEARCH ROUNDTABLE

A MESSAGE FROM THE HOST OF THE RESEARCH ROUNDTABLE

by Lisa Thompson

The Department of Research Programs (DRP) would like to offer a 10-15 minute presentation to your staff. Our talk ranges from DRP services to upcoming events and policy updates from the Office of the Under Secretary of Defense [(Personnel & Readiness and Research Regulatory Oversight Office (R202)], a review of the Minimum Education Requirements Framework (MERF) issued by the Office of the Assistant Secretary of Defense for Research and Engineering, and information on required Collaborative Institutional Training Initiative (CITI) training. We would like to join you annually or every six months, before or after your program meets for didactic or lecture hall sessions.

Our goal is to promote research. We want to help familiarize your Graduate Medical Education (GME) trainees, faculty, and staff with DRP services to help them meet their research and scholarly project program requirements.

Our services include assistance with protocol development, courses on research methods, statistics, and grant writing, GME trainee research project funding opportunities, collaborative agreements development, manuscript editing, publication clearance, and bench research space through our Biomedical Research Laboratory.

DRP invites you to join us at the Research Roundtable on the third Tuesday of every month at noon. On March 21, Diane Beaner, DRP's research compliance officer, will address, "What Are Essential Regulatory Documents: Where Are These Documents Kept?"

We invite you to present as well. If there is a pressing concern you would like addressed or if you would like to present material on a topic of your choice, please talk to me at the Research Roundtable or send an email to lisa.p.thompson5.civ@mail.mil. □



Lisa Thompson,
supervisory medical
education specialist
(Photo by subject)

Evers: Military merits kudos for safeguarding subjects

by Paula Amann

Over more than 100 years, the military medical system has largely worn the proverbial white coat when it comes to defending the interests of human research subjects, argued chemist David Evers at the Research Roundtable on Feb. 22.

"I think we have a lot to be proud of; you have a lot to be proud of," Evers said. His talk, "Research Ethics: Great Moments in Military Human Subject Research Protections," led the audience on a ramble through medical history studded with legal cases and patient vignettes.

During the 20th century, the armed forces pioneered vaccine studies for infectious diseases. The research ranged from yellow fever and typhoid fever in the early decades, to later work on rabies and diphtheria, to efforts in the century's second half on pneumococcus, rubella, meningococcus and Hepatitis B.



David Evers, a chemist with the Department of Research Programs, took the Research Roundtable on a journey through military medical ethics. (Photo by Paula Amann)

In the thick of recent studies on tropical medicine was Army Col. Peter Weina, chief of the Department of Research Programs.

A 2013 editorial for PLOS – Neglected Tropical Diseases, "United States Military Tropical Medicine: Extraordinary Legacy, Uncertain Future," by Coreen Beaumier and three other researchers, including Weina, summed up these efforts.

"Consistently throughout the 20th and into the 21st century, the health and military impact of these tropical infections has approached or exceeded that resulting from battlefield injuries," Beaumier et al. reported.

What's more, she and her colleagues note the humanitarian impact of military medical research. While protecting U.S. troops, this knowledge has been "simultaneously aiding and empowering the world's poor who are also plagued by these debilitating diseases," Beaumier et al. wrote.

See KUDOS, page 13



KUDOS, from page 12

Like other medical scientists, military researchers have relied on ethical principles such as informed consent to guide their work. As part of his slide show, Evers shared bilingual consent forms from Nov. 26, 1900, signed by Antonio Benigno, aged 25, for a study of yellow fever in Cuba.

These documents pledged compensation of \$100, with another \$100 promised if Benigno contracted the fever. The other signature on the forms was that of legendary medical researcher, Walter Reed, who led the study.

In a later episode that sharply broke with ethics, a Tuskegee Army board agreed over 1941-42 to cooperate with researchers who studied African-American men with syphilis, while withholding treatment for them.

Before this collaboration, though, the board sent reminders to some subjects “to begin their antisypilitic treatment immediately,” according to the 1973 Final Report of the Tuskegee Syphilis Ad Hoc Advisory Board.

A decade later, in 1953, psychologist John Kobrick was aiding in research at the U.S. Army Quartermaster Research and Development Command in Natick, Massachusetts.

“Things were simpler then, but we still followed the rules of informed consent,” recalled Kobrick, quoted in *Military Medical Ethics*, Volume 2. “We knew what was right and we just did it.”

Decades before a 1973 U.S. court case first citing the Nuremburg Code, the ethical rules drafted in reaction to

Nazi atrocities during World War II, the 1953 Wilson Memorandum mandated the code for the U.S. Department of Defense, Evers noted in his remarks.

A decade later, in 1954, the Army recruited members of a pacifist religious sect, the Seventh-Day Adventist Church, to take part in Operation Whitecoat. This research venture grew into 20-year study of vaccines against biological weapons with 2,000 participants.

By today’s standards, the informed consent forms used fell short of complete protections. However, participants did sign a consent form, and in keeping with current medical ethics, could quit the experiment at any time.

Researchers followed up on the health of 164 volunteer controls compared with 358 “exposed” subjects, according to a 2005 article in *Military Medicine* by Army Col. Dr. Phillip R. Pittman et al. Their findings showed a lack of significant difference in morbidity between these two groups.

Sifting through recent history, Evers portrayed the U.S. military, medical research as proactive, rather than reactive, in its ethics. From the principles of beneficence and informed consent to adoption of the Common Rule, a set of research ethics used by much of the federal government, the armed forces has kept pace with and often led the civilian world, he said. ▣

TRAINING FOR RESEARCHERS

Ready for research? The Department of Research Programs has the right training for your role. We offer workshops for researchers working with human subjects:

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- April 10, 2-3 p.m., Computer Classroom 2 (4011)
- May 8, 2-3 p.m., Computer Classroom 2 (4011)

Questions? Please contact Ms. Lisa Thompson, supervisory research education specialist, at 301-295-8231 or lisa.p.thompson5.civ@mail.mil.

You belong in the CITI. Start training today!



RECENT PUBLICATIONS

Courtesy of Darnall Medical Library

Find articles by authors at Walter Reed Bethesda in bold.

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PUBLICATIONS, from page 14

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The appearance of external hyperlinks does not constitute endorsement by the U.S. Department of Defense of the linked web sites, or the information, products or services contained therein. For other than authorized activities such as military exchanges and Morale, Welfare and Recreation (MWR) sites, the Defense Department does not exercise any editorial control over the information you may find at these locations.

Education Materials

- [Belmont Report](#)

The Belmont Report provides "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" that is found in Code of Federal Regulations, 45 CFR part 46.

- [Comparison of FDA and HHS Regulations](#)

The FDA provides a chart comparing FDA's regulations for human subject protection with those of the Department of Health and Human Services.

- [The President's Council on Bioethics](#)

This web site provides useful references on ethical issues that arise from advances in biotechnology and biomedical sciences.

- [Clinical Trials.gov](#)

Clinical Trials is a service of the National Institutes of Health, provides free public access to a database of Federal and private studies taking place nationwide and provides information on clinical studies for a wide range of diseases and conditions.

- [HHS Office for Human Research Protections](#)

HHS OHRP provides assurances and IRB registration, education, policy guidance, and workshops.

- [HHS Office of Civil Rights](#)

HHC Office of Civil Rights provides guidance on the Health Insurance Portability and Accountability Act (HIPAA) and Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule).

- [MedlinePlus](#)

MedlinePlus provides medical research literature including full-text drug information and an illustrated medical encyclopedia.

- [Office for Human Research Protections \(OHRP\)](#)

OHRP Guidebook (1993) provides current and historical materials about human subject protection. Caution: this serve as a guide and some information is obsolete; however, some portions remain valid.

- [Federal Policy for the Protection of Human Subjects \('Common Rule'\)](#)

HHS provides information about HHS regulations, 45 CFR part 46 and four subparts a, b, c, and d.

- [Protocol Review](#)

HHS provides guidance for protocol development, use of IRB, and Expedited Review procedures and exemptions.

- [Informed Consent](#)

HHS provides informed consent requirements, guidance on the use of exculpatory language, legal obligation and penalties, documentation and changes to documentation.

- [Investigators](#)

HHS provides investigators guidance about emergency medical care and research.

- [Biological Material and Data](#)

HHS provides guidance and the law about research involving the use of biological material and data.

- [Vulnerable Populations](#)

HHS provides guidance for populations including prisoners, children, and HIV human subjects.

FDA Regulations

- [CFR – Code of Federal Regulations Title 21](#)

- [FDA Regulations Relating to Good Clinical Practice and Clinical Trials](#)

- [Preambles to GCP Regulations](#)

- [Electronic Records; Electronic Signatures \(21 CFR Part 11\)](#)

- [Regulatory Hearing Before the Food and Drug Administration \(21 CFR Part 16\)](#)



*Walter Reed National Military Medical Center
Department of Research Programs*

TRAINING FOR ELECTRONIC INSTITUTIONAL REVIEW BOARD (EIRB)

QUESTION AND ANSWER SESSIONS

Mondays 1200–1300

Month	Dates Radiology Conference Room B015, Building 19, Basement
March	13 20 27
April	3 10 17 24
May	1 8 15 22
June	5 12 19 26
July	3 10 17 24 31
August	7 14 21 28



*The Department of Research Programs at
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2017 RESEARCH AND INNOVATION MONTH *Be a research hero — and more.*

IMPORTANT DATES

Poster Display Week

▣ 01–05 May

All competition participants display their research posters in the Mezzanine Center, East, and West Wings of Building 9. Posters based on Unity of Effort will carry its logo in the upper right corner. Unity of Effort reflects the partnerships among Walter Reed National Military Medical Center (Walter Reed Bethesda) and its neighbors, the Uniformed Services University of the Health Sciences and the National Institutes of Health.

▣ 03 May – Poster Competition I (Case Reports, Evidence-Based Practice, and Quality Improvement)

Finalists from non-research competition categories present their posters to judges in Building 9, East Wing. Award ribbons will be pinned next to the winning posters of each research competition category.

▣ 04 May – Poster Competition II (Paul Florentino Patient and Family-Centered Care)

Participants in this category will present their project posters for first, second, and third prizes in Building 9.

Research Symposia I and II

▣ 09–10 May

Finalists for the Bailey K. Ashford and Robert A. Phillips research awards present slides on their work before judges in Memorial Auditorium, Building 2, third floor. Winners receive certificates and medallions. Also, winners of Poster Competitions I and II will present.

5th Annual Aware for All

▣ 16 May

Aware for All aims to help the public make informed decisions about clinical research participation through speakers and display tables. Research teams at Walter Reed Bethesda and groups from the National Capital Region showcase their work in the lobby of Building 19.

Spring Research Summit

▣ 24 May

Research-related groups present slides, share information, and network about their work at Memorial Auditorium, Building 2, third floor.

*For details on Research and Innovation Month,
contact the Department of Research Programs:*

dha.bethesda.wrnmcc.mbx.researchandinnovationmonth@mail.mil

